

PATENT



## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants : William B. Cowden et al.  
Application No. : 09/142,597  
Filed : March 5, 1999  
For : USE OF COXIELLA BACTERIA TO TREAT AUTOIMMUNE DISEASE

Examiner : S. Devi, Ph.D.  
Art Unit : 1645  
Docket No. : 120081.403C1

Box Patent Application  
Commissioner for Patents  
Washington, DC 20231

INFORMATION DISCLOSURE STATEMENT

## Commissioner for Patents:

In accordance with 37 C.F.R. §§ 1.56 and 1.97 through 1.98, applicants wish to make known to the Patent and Trademark Office the references set forth on the attached forms PTO-1449. Applicants will submit references if the Examiner desires. This application relies, under 35 U.S.C. § 120, on the earlier filing date of prior U.S. Application 09/142,597, filed March 5, 1999 and International Application No. PCT/AU97/00161, filed March 14, 1997. As to any reference supplied, applicants do not admit that it is "prior art" under 35 U.S.C. §§ 102 or 103, and specifically reserve the right to traverse or antedate any such reference, as by a showing under 37 C.F.R. § 1.131 or other method. Although the aforesaid references are made known to the Patent and Trademark Office in compliance with applicants' duty to disclose all information they are aware of which is believed relevant to the examination of the above-identified application, applicants believe that their invention is patentable.

Please acknowledge receipt of this Information Disclosure Statement and kindly make the cited references of record in the above-identified application.

Respectfully submitted,

Seed Intellectual Property Law Group PLLC



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Enclosures:

Forms PTO-1449 (2 sheets)

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FORM PTO-1449 (REV.7-80)		U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE		ATTY. DOCKET NO. 120081.403C1	Express Mail No. EL 755624161US
<b>INFORMATION DISCLOSURE STATEMENT</b> <i>(Use several sheets if necessary)</i>		APPLICANTS			
		William Butler Cowden et al.		FILING DATE June 19, 2001	

10088888773  
 06/21/01

### U.S. PATENT DOCUMENTS

*EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	AA						

### FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	TRANSLATION
					YES      NO
	AB				

### OTHER PRIOR ART *(Including Author, Title, Date, Pertinent Pages, Etc.)*

AC	Atkinson et al., "Are Insulin Autoantibodies Markers for Insulin-Dependent Diabetes Mellitus?", <i>Diabetes</i> 35:894-898, August 1986.
AD	Bach, "Insulin-Dependent Diabetes Mellitus as an Autoimmune Disease," <i>Endocrine Reviews</i> 15(4):516-542, 1994.
AE	Bowen et al., "Successful Allogeneic Transplantation of Mouse Pancreatic Islets to Nonimmunosuppressed Recipients," <i>Diabetes</i> 29(suppl. 1):98-104, February 1980.
AF	Davis et al., "The Role of Polymorphic I-A <sup>k</sup> $\beta$ Chain Residues in Presentation of a Peptide from Myelin Basic Protein," <i>J. Exp. Med.</i> 169:2239-2244, June 1989.
AG	Gross et al., "Prevention of Diabetes Mellitus in Non-Obese Diabetic Mice by Linomide, a Novel Immunomodulating Drug," <i>Diabetologia</i> 37:1195-1201, 1994.
AH	Harada et al., "Prevention of Overt Diabetes and Insulitis in NOD Mice by a Single BCG Vaccination," <i>Diabetes Research and Clinical Practice</i> 8:85-89, 1990.
AI	Honeyman and Harrison, "The Immunologic Insult in Type 1 Diabetes," <i>Springer Seminars in Immunopathology</i> 14:253-274, 1993.
AJ	Kanazawa et al., "Non-Obese-Diabetic Mice: Immune Mechanisms of Pancreatic $\beta$ -Cell Destruction," <i>Diabetologia</i> 27:113-115, 1984.
AK	Lakey et al., "Prevention of Recurrence of Insulin-Dependent Diabetes Mellitus in Islet Cell-Transplanted Diabetic NOD Mice Using Adjuvant Therapy," <i>Transplantation Proceedings</i> 24(6):2848, December 1992.
AL	Lakey et al., "BCG Immunotherapy Prevents Recurrence of Diabetes in Islet Grafts Transplanted into Spontaneously Diabetic NOD Mice," <i>Transplantation</i> 57(8):1213-1217, April 1994.
AM	Makino et al., "Breeding of a Non-Obese, Diabetic Strain of Mice," <i>Exp. Anim.</i> 29(1):1-13, 1980.

EXAMINER	DATE CONSIDERED

\* EXAMINER: Initial if reference considered, whether or not criteria is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant(s).

U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE			ATTY. DOCKET NO. 120081.403C1	Express Mail No. EL 755624161US
INFORMATION DISCLOSURE STATEMENT (Use several sheets if necessary)			APPLICANTS William Butler Cowden et al.	FILING DATE June 19, 2001
			GROUP ART UNIT 1645	

10659/88777  
 06/21/01  
 PTO

## U.S. PATENT DOCUMENTS

*EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	BA						
	BB						
	BC						
	BD						

## FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	TRANSLATION
					YES
	BE				
	BF				
	BG				

## OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)

BH	McInerney et al., "Prevention of Insulitis and Diabetes Onset by Treatment With Complete Freund's Adjuvant in NOD Mice," <i>Diabetes</i> 40:715-725, June 1991.
BI	Qin et al., "Mechanisms of Complete Freund's Adjuvant Protection Against Diabetes in BB Rats: Induction of Non-Specific Suppressor Cells," <i>Autoimmunity</i> 12:193-199, 1992.
BJ	Sadelain et al., "Prevention of Type I Diabetes in NOD Mice by Adjuvant Immunotherapy," <i>Diabetes</i> 39:583-589, May 1990.
BK	Sadelain et al., "Prevention of Diabetes in the BB Rat by Early Immunotherapy Using Freund's Adjuvant" <i>Journal of Autoimmunity</i> 3(6):671-680, December 1990.
BL	Shehadeh et al., "Altered Cytokine Activity in Adjuvant Inhibition of Autoimmune Diabetes," <i>J. Autoimmunity</i> 6(2):291-300, April 1993.
BM	Ulaeto et al., "A T-Cell Dormant State in the Autoimmune Process of Nonobese Diabetic Mice Treated with Complete Freund's Adjuvant," <i>Proc. Natl. Acad. Sci. (USA)</i> 89(9):3927-3931, May 1992.
BN	Wang, et al., "Prevention of Recurrence of IDDM in Islet-Transplanted Diabetic NOD Mice by Adjuvant Immunotherapy," <i>Diabetes</i> 41(1):114-117, January 1992.
BO	Yagi et al., "Possible Mechanism of the Preventive Effect of BCG Against Diabetes Mellitus in NOD Mouse: II. Suppression of Pathogenesis by Macrophage Transfer from BCG-Vaccinated Mice," <i>Cellular Immunology</i> 138(1):142-149, 1991.

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